

REMARKS / ARGUMENTS

In the above-identified Office Action the Examiner has rejected claims 5 and 9 as anticipated by Applezwaig and claims 5-7 and 9 have been rejected as unpatentable over Xia et al. in view of Roberts.

In the Examiner's response to the previous Amendment, he indicated that the claims should be limited to patients in need thereof. Further, the route of administration, i.e., orally, should be inserted. Finally, the use of the term "about" was suggested as requiring removal. Applicant has done all of the above, i.e., Claim 9 now reads that it comprises the oral administration to a human or non-human animal in need thereof of an effective amount of an active agent and dosage range of 0.1 to 25 mg/kg bodyweight. As such, Applicant believes that the unexpected results discussed at the previous interview are the result of unexpectedly improved results and are not taught by the prior art.

The above claimed dosage range is a reasonable extrapolation from the data in that it is reasonably expected that some latitude around the tested effective dosage is still effective, especially where the dosage is being increased but also when it is being reduced to an extent. The claimed dosage is for each administration but is still commensurate with a per day dosage in the experimental work. Dosing of humans for treatment of ALS, a severe neurodegenerative condition characterized by paralysis will be regular, typically on about the per day time scale, to avoid the physiological concentration of the active falling to ineffective levels; some flexibility will be required as the optimal regiment will be worked out according to the particular oral form marketed and, to some extent, according to the patient's individual requirements. Generally, daily dosing of humans with severe medical conditions is normal and it is not reasonable to read the claim in such a way that the claimed total daily dose could depart substantially from the evidence relating to the tested, effective dose.

Application No. 10/507,000
Amdt. dated 8 November 2010
Reply to Office Action of 17 August 2010

Accordingly, Applicant believes that the subject invention, as now claimed, is patentable.

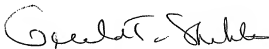
Applicant hereby requests reconsideration and reexamination thereof.

No further fee or petition is believed to be necessary. However, should any further fee be needed, please charge our Deposit Account No. 23-0920, and deem this paper to be the required petition.

With the above amendments and remarks, this application is considered ready for allowance and applicant earnestly solicits an early notice of same. Should the Examiner be of the opinion that a telephone conference would expedite prosecution of the subject application, he/she is respectfully requested to call the undersigned at the below listed number.

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Respectfully submitted,

A handwritten signature in black ink, appearing to read "Gerald T. Shekleton". The signature is fluid and cursive, with the first name "Gerald" being more prominent and the last name "Shekleton" following in a similar style.

Dated: 8 November 2010

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